SEP 12 2012

510(k) Summary, Section 807.92(a)(2) K120277

Submitted by	Lung Assist, Inc. 4655 Kirkwood Court Boulder, CO 80301

Contact Person	Lewis Ward Vice President Operations 4655 Kirkwood Court Boulder, CO 80301 303-516-1024 303-530-4774 Fax lwward@qwest.net

Date Prepared	August 15, 2012

Product Name	Trade Name: Vital Cough Common Name: Cough Assist Device

Classification	Noncontinuous Ventilator 868.5905, Product Code NHJ Class II

Intended Use	The Vital Cough is intended for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in a hospital, institutional setting, or home use given adequate training. For use on adult or pediatric patients.

Technological Characteristics	The device is an electromechanical software controlled device housed in a metal and polymer case. A touch screen displays outputs and receives commands from the user. The device develops positive and negative pressure through an adjustable blower. In inhale mode the lungs are inflated. The device rapidly shifts to providing negative pressure with the intended goal of rapidly deflating the lungs to stimulate an effective patient cough.

Non-clinical Testing	The Vital Cough complies with the IEC 60601-1 general requirements for electrical safety and IEC 60601-1-2 electromagnetic compatibility standards. No toxic substances have been found in the output air of the device. The device conforms to ISO 9703 anesthesia and respiratory care alarm signals, auditory and visual.

Substantial Equivalence	The Vital Cough is substantially equivalent to the Emerson Cough Assist device (K002598). The modes, frequency, output, and indications for use are equivalent. Differences are safety related and upgrades to current technologies.

Key Feature Comparison, MI-E Device

Feature	Emerson Cough Assist	Vital Cough
Positive Pressure	+60 cm H_2O	+50 cm H_2O
Negative Pressure	-60 cm H_2O	-50 cm H_2O
Maximum Inhalation Flow	3.3 liters/sec published 5.5 liters/sec measured	7.3 liters/sec
Maximum Exhalation Flow	10 liters/sec published 6.4 liters/sec measured	7.7 liters/sec
Mode of Operation	Mechanical switch control	Software controlled
Patient Use	Adult and pediatric, hospital or institution environment or in the home given adequate training a physicians' prescription	Adult and pediatric, hospital or institution environment or in the home given adequate training a physicians' prescription

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2012

Lung Assist, Incorporated
Mr. Lewis Ward
Vice President Operations
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K120277
Trade/Device Name: Vital Cough
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: August 17, 2012
Received: August 31, 2012

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120277

Device Name: Vital Cough

Indications for Use:

The Vital Cough is intended for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in a hospital, institutional setting, or home use given adequate training. For use on adult or pediatric patients.

Prescription Use _X_ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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